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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/188, 051 11/06/98 SHIRLEY

B 5784-25

CHIRON CORPORATION  
INTELLECTUAL PROPERTY DEPT.  
4560 HORTON STREET  
EMERYVILLE CA 94608-2916

HM22/0123

EXAMINER

MOEZIE, F

ART UNIT	PAPER NUMBER
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1653

DATE MAILED:

19

01/23/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademark**

## Office Action Summary

Application No. 09/188,051	Applicant(s) Shirley et al
Examiner F. T. Moezie	Group Art Unit 1653

Responsive to communication(s) filed on Nov 13, 1900

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 29-84 is/are pending in the application.

Of the above, claim(s) 49-84 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 29-48 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 29-84 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been  received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### **STATUS OF CLAIMS**

New claims 29 to 48 are pending prosecution in this Office action.

Claims 1-28 were originally been filed (11/06/98). Upon filing of CPA claims 1-28 were canceled and claims 29-84 were added (12/13/99, paper no. 13).

Claims 29-84 were restricted to three Groups of Inventions (10/12/00, paper no. 16).

Applicant elected Group II invention, claims 29-48, drawn to a composition comprising;  
a) a biologically active IGF-I or analogue thereof and b) a solubilizing compound comprising a guanadinium group, without traverse (11/13/00).

In response to the Species Election, applicant elected "arginine as the species of guanidinium-group containing compound" paper no. 17, received 13 November 2000.

Claims 49-84, drawn to non-elected Inventions are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 17, received 13 November 2000.

The restriction requirement is made **FINAL**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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**REJECTION - 35 USC 103 (a)**

Claims 29-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al.

Chang et al teach that; the solubility of the isolated insoluble IGF-I is increased using a single buffer containing a chaotropic agent. See, the paragraph bridging column 26-27.

Moreover, at column 10, the typical pH range for the buffer and the chaotropic agents suitable for increasing the solubility of and IGF-I or an analogue thereof in solution are also taught.

Hence, the reference clearly shows that the use of guanidinium-containing compounds enhance the solubility of IGF-I at higher pH (pH of typically at least 7.5), thereby providing for a stable IGF-I composition having higher concentrations. See the entire document.

It would have been obvious to an ordinary art skilled at the time the invention was made to use the conditions cited by the reference for obtaining a composition of IGF-I or analogues thereof with higher concentration of the active agent(s) therein - as claimed. To choose a particular concentration range (mg/ml) is well within the skill of an ordinary art skilled and greatly depends on the use for the resulting composition.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508.

*J. J. Moezie*  
F. T. MOEZIE  
MARY EXAMINER  
ART UNIT 1653